

Remarks/Arguments

Claims 39-43 are pending in this application. Claim 39 has been amended for clarity. No new matter has been added by way of this amendment and its entry is respectfully requested.

Request for consideration of change of address

A revocation of Power of Attorney and change of address was mailed to the USPTO in this case on February 20, 2003. A stamped, return postcard was received from the USPTO dated February 27, 2003. Applicants respectfully request that the Examiner note the address change and kindly direct all correspondence pertaining to this case to:

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Claim Objections

Claim 39 has been amended to correct an informality as suggested by the Examiner.

Claim Rejections – 35 USC § 101

Claims 39-43 remain rejected under 35 U.S.C. §101 for lack of a specific, substantial and credible utility.

The Examiner states that “(t)he only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.” The Examiner does not find the Declaration by Dr. Fong persuasive. While the Examiner agrees that “(t)here appears to be no disagreement on the role of proinflammatory molecules as presented in the Declaration of Fong and the view existing in the art,” the Examiner argues that “...proinflammatory proteins.... are known to play a key role in the migration of inflammatory cells in autoimmune diseases and in invasive cancers.” “it is also recognized in the art that the spectrum of action of proinflammatory molecules is very broad and also dependent on the timing and level of production of a specific proinflammatory protein.” Based on the review article by Falcone *et al.*,

the Examiner points out that “the art acknowledges the broad range and complexity of functions of proinflammatory proteins and, therefore, the specific function of a particular molecule cannot be predicted based solely on the notion that it belongs to a family of proinflammatory proteins.” (Emphasis added). From these statements, it seems that, while the Examiner acknowledges that a proinflammatory molecule may play a role in diseases such as, for example, in autoimmune diseases, invasive cancers, etc., the 'specific function' of a particular proinflammatory molecule cannot be predicted based solely on the notion that it belongs to a family of proinflammatory proteins. Applicants respectfully submit that the Examiner's position on “utility requirements” for a molecule is legally incorrect, and respectfully traverse this rejection.

Utility – Legal Standard

The well established case law is clearly reflected in the Utility Examination Guidelines (“Utility Guidelines”)¹, which acknowledge that an invention complies with the utility requirement of 35 U.S.C. §101, if it has at least one asserted “specific, substantial, and credible utility” or a “well-established utility.” The case law has also clearly established that applicants’ statements of utility are usually sufficient, unless such statement of utility is unbelievable on its face.² The PTO has the initial burden that applicants’ claims of usefulness are not believable on their face.³ In general, an Applicant’s assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101, “unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.”^{4, 5} The Utility Guidelines also restate the Patent Office’s long established position that:

¹ 66 Fed. Reg. 1092 (2001).

² *In re Gazave*, 379 F.2d 973, 154 U.S.P.Q. (BNA) 92 (C.C.P.A. 1967).

³ *Ibid.*

⁴ *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. (BNA) 288, 297 (CCPA 1974).

⁵ *See, also In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (1965); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

“by statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit.”

The Utility Guidelines further state that:

“the record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the Examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities or related inventions. Thus, even when the Examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities.a well-established utility is a specific, substantial and credible utility that must be readily apparent to one skilled in the art”⁶ (Emphasis added).

Under the Utility Guidelines, a utility is “specific” when it is particular to the subject matter claimed. For example, it is generally not enough to state that a particular composition of matter is useful as a diagnostic tool, without also identifying the conditions that are to be diagnosed using the diagnostic tool. However, when the condition that is capable of being diagnosed is specifically identified and linked to the claimed subject matter, the asserted utility satisfies the “specificity requirement.”

Later, in *Nelson v. Bowler*⁶ the CCPA acknowledged that tests evidencing pharmacological activity of a compound may establish practical utility, even though they may not establish a “specific” therapeutic use. The court held that “since it is crucial to provide researchers with an incentive to disclose pharmaceutical activities in as many compounds as possible, we conclude adequate proof of any such activity constitutes a showing of practical utility.”⁷ (Emphasis added).

⁶ *Nelson v. Bowler*, 626 F. 2d 853, 206 U.S.P.Q. (BNA) 881 (C.C.P.A. 1980).

⁷ *Id.* at 856. 206 U.S.P.Q. (BNA) at 883.

In *Cross v. Iizuka*⁸ the CAFC reaffirmed *Nelson*, and added that in vitro results might be sufficient to support practical utility, explaining that “in vitro testing, in general, is relatively less complex, less time consuming, and less expensive than in vivo testing (emphasis added). Moreover, in vitro results with the particular pharmacological activity are generally predictive of in vivo test results, i.e. there is a reasonable correlation there between.”⁹ The court perceived “No insurmountable difficulty” in finding that, under appropriate circumstances, “in vitro testing, may establish a practical utility.”¹⁰

In interpreting the “substantial utility” requirement, in *Brenner v. Manson*¹¹ the Supreme Court held that the quid pro quo contemplated by the U.S. Constitution between the public interest and the interest of the inventors required that a patent applicant disclose a “substantial utility” for his or her invention, i.e. a utility “where specific benefit exists in currently available form.”¹² The Court concluded that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. A patent system must be related to the world of commerce rather than the realm of philosophy.”¹³

In explaining the “substantial utility” standard, M.P.E.P. §2107.01 cautions, however, that Office personnel must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy the utility requirement. “Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard

⁸ *Cross v. Iizuka*, 753 F.2d 1047, 224 U.S.P.Q. (BNA) 739 (Fed. Cir. 1985).

⁹ *Id.* at 1050, 224 U.S.P.Q. (BNA) at 747.

¹⁰ *Id.*

¹¹ *Brenner v. Manson*, 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

¹² *Id.* at 534, 148 U.S.P.Q. (BNA) at 695.

¹³ *Id.* at 536, 148 U.S.P.Q. (BNA) at 696.

to defining a “‘substantial’ utility”¹⁴ (emphasis added). Indeed, the Guidelines for Examination of Applications for Compliance With the Utility Requirement,¹⁵ gives the following instruction to patent examiners:

“If the applicant has asserted that the claimed invention is useful for any particular practical purpose . . . and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.”

Moreover, the Utility Guidelines make clear that the requirement for the asserted utility be “substantial” arises solely for the purpose of excluding:

“‘throw-away’ or ‘insubstantial’ . . . utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. §101.”¹⁶ (emphasis added).

Proper Application of the Legal Standard

The data presented in the present application, upon which applicants rely for utility and is currently disputed, is presented in Example 77 (page 210, lines 22- “skin vascular permeability assay”), which is a well-described, dye-based assay routinely employed to identify proinflammatory molecules that cause the influx or infiltration of proinflammatory cells into a site of vascular leakage (or edema). In other words, a positive hit for PRO266 in the proinflammatory assay allows one skilled in the art to use PRO266 as a therapeutic target, since using PRO266 “to recruit proinflammatory cells into say, a tumor site” is useful to prevent tumor invasiveness, and/or possibly, to destroy tumor cells. Alternatively, blocking its function would be useful to ‘decrease’ inflammation, for instance, in autoimmune diseases. The latter application is more specific to the instantly claimed invention, and thus antagonistic antibodies to PRO266 are part of the invention here and are at least useful for “decreasing” inflammation in

¹⁴ M.P.E.P. §2107.01.

¹⁵ M.P.E.P. §2107 II(B)(1).

¹⁶ 66 Fed. Reg. 1092, 1098 (2001).

disease conditions like autoimmune diseases. Therefore, the skilled artisan would readily recognize a utility for the PRO266 polypeptide and its antibodies based on its positive hit in the proinflammatory skin vascular permeability assay.

Contrary to the Applicants assertion of utility herein, however, the Examiner alleges that the positive hit in the skin vascular permeability assay does not render the presently claimed antibodies patentably useful. Applicants respectfully submit, however, that upon application of the appropriate legal standards described above, the proper conclusion is that the present application does, in fact, disclose a patentable utility for the claimed invention.

(i) The Requirement for a “specific” utility

As described above, Applicants have clearly demonstrated that PRO266 is detectably a proinflammatory molecule based on the skin vascular permeability assay. In the non-final Office action of January 3, 2005, the Examiner asserts:

“the ‘specific **function**’ of a particular proinflammatory molecule cannot be predicted based solely on the notion that it belongs to a family of proinflammatory proteins.”

(Emphasis added).

Applicants respectfully submit that a ‘specific **function**’ to be disclosed for patentable molecule is not a requirement for “specificity” under 35 U.S.C. § 101. Even if a proinflammatory protein may have a “broad range and complexity of functions” and “a specific function” of a particular proinflammatory molecule cannot be predicted, prediction of specific function is not a utility requirement. As described above, the “specificity” requirement under 35 U.S.C. § 101 merely requires a patent applicant to set forth and describe the asserted utility with specificity. Applicants have asserted that the claimed invention is specifically useful as “a therapeutic target” at least to prevent tumor invasiveness, and/or possibly, to destroy tumor cells or alternatively, antagonistic antibodies to PRO266 are useful to ‘decrease’ inflammation, for instance, in autoimmune diseases. Applicants have specifically identified and described diseases for which the invention is therapeutically useful. Therefore, applicants respectfully submit that this clearly satisfies the “specificity requirement”.

(ii) The Requirement for a “substantial” utility

As described above, as set forth in the Utility Guidelines, for a claimed invention to be “substantial,” the claimed invention must serve a “practical purpose” which is not a “throw-away or insubstantial [use], such as the use of a complex invention as a landfill”¹⁷ (Emphasis supplied).

In this regard, the Examiner states:

“It is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. In the instant case, significant further research would have to be conducted to identify diseases, which could be treated by administration of antibodies to PRO266 proteins.”

Applicants strongly disagree. In essence, the Examiner’s argument is that being able to identify PRO266 as a therapeutic proinflammatory target is (i) “impractical”, (ii) a “throw-away” use which is akin to the use of “a complex invention as a landfill”, and is (iii) “insubstantial”. Applicants respectfully submit that there is nothing farther from the truth. Scientific and medical researchers spend millions of dollars each year to develop new, and useful proinflammatory therapeutic targets which are useful for treating invasive cancers or antagonistic antibodies that are useful against autoimmune diseases. The discovery of PRO266 as a proinflammatory molecule provides for the first time the ability to exploit this target as a therapeutic agent for treating the above mentioned diseases. This does not mean that the invention is not useful in its currently available form. As such, Applicants reiterate the M.P.E.P. §2107.01 which cautions, however, that

“Office personnel must be careful not to interpret the phrase “immediate benefit to the public” or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must be “currently available” to the public in order to satisfy the utility requirement. “Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be

¹⁷ 66 Fed. Reg. 1092, 1098 (2001).

accepted as sufficient, at least with regard to defining a “‘substantial’ utility” (emphasis added).

Applicants submit that the utility presently asserted for the claimed invention meets the “substantial” requirement set for by the Utility Guidelines and required by the U.S. Supreme Court in Brenner v. Manson, 383 U.S. 519 (1966).

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present utility rejection.

Claims Rejections - 35 USC § 112, First Paragraph

Claims 39-43 are rejected under 35 U.S.C. §112, first paragraph, since allegedly, the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, thus one skilled in the art would not know how to use the claimed invention.

As discussed above, antibodies to PRO266 are useful at least as anti-inflammatory agents. Therefore, one skilled in the art would not know how to make and use the claimed antibodies to treat inflammatory conditions based on the instant disclosure and the advanced knowledge of the skilled artisan in the art. Accordingly, Applicant respectfully request the Examiner to withdraw this rejection under 35 U.S.C. §112, first paragraph.

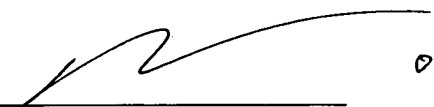
The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C30).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: July 5, 2005



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